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k 003553

MAR 21 2001

BD

Indispensable to human health

Summary of Safety and Effectiveness for the 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringe:

1 BD Contact person:

Gregory W. Morgan
Director, Regulatory Affairs
BD Medical – Mail Code 226
1 Becton Drive
Franklin Lakes, NJ 07417-1880
Phone (201) 847-4344
Fax (201) 847-4855

2 Device Name: 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringe

3 Predicate Device(s):

3.1 Vital Signs Saline Vascular Access Flush Device K952645
3.2 BD Preefil™ Normal Saline Flush Syringe K982558

4 Product Description / Function:

Product sizes/reorder numbers: The following sizes/reorder numbers of the 0.9% Sodium Chloride Injection USP, BD Pre-Filled Flush syringes to be offered are:

- 2ml Syringe — Reorder Number: 306543
- 3ml Syringe — Reorder Number: 306544
- 5ml Syringe — Reorder Number: 306545
- 10ml Syringe with regular plunger rod — Reorder Number: 306546
- 10ml Syringe — Reorder number: 306547

Reorder Numbers 306543, 306544, 306545 and 306547 all have "Short" plunger rods which "discourage re-use". Plunger rods bottom against syringe barrel flange after flush, and are difficult to pull back therefore they discourage re-use. Also as the plunger rod bottoms against the syringe barrel flange it minimizes stopper compression which reduces reflux produced by the syringe. This feature is called zero compression. Reorder number 306546 (10ml syringe with 10ml fill) comes with a regular length plunger rod that does not have "discourage re-use"

and zero compression features. The regular length plunger rods do not bottom against the syringe barrel flange to allow the user to aspirate after flush.

Intended Uses: The 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringes are intended for use in maintaining patency of vascular accesses devices (VAD'S).

5 Equivalence determination:

The elements of comparison between the 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringes and BD Preefil™ Normal Saline Flush Syringe and Vital Signs Saline Vascular Access Flush Device predicate devices are as follows:

- The 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringe contains 0.9% Sodium Chloride Injection, USP solution as does the predicate devices.
- The 0.9% Sodium Chloride, Injection USP BD Pre-Filled Flush Syringe has a sterile solution as do the predicate devices.
- The 0.9% Sodium Chloride, Injection USP BD Pre-Filled Flush Syringe is terminally sterilized as the predicate device, Vital Signs.
- The 0.9% Sodium Chloride, Injection USP BD Pre-Filled Flush Syringe is a three-piece piston design as is the predicate device, BD Preefil™.
- The 0.9% Sodium Chloride, Injection USP BD Pre-Filled Flush Syringe barrel is molded from polypropylene as is the predicate device, BD Preefil™.
- The 0.9% Sodium Chloride, Injection USP BD Pre-Filled Flush Syringe has a similar package unit design as the predicate device, BD Preefil™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2001

Mr. Gregory W. Morgan
Head of Regulatory Compliance
BD Becton Dickinson Vacutainer Systems Preanalytic
BD Medical Injection Systems
1 Becton Drive
Mail Code 226
Franklin Lakes, New Jersey 07417

Re: K003553
Trade Name: 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringes
Regulatory Class: II
Product Code: FOZ
Dated: February 23, 2001
Received: February 26, 2001

Dear Mr. Morgan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

The 0.9% Sodium Chloride Injection, USP BD Pre-Filled Flush Syringes are intended for use in maintaining patency of vascular access devices (VAD's).

(Revised 3/21/01)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K005553